

### REMARKS

The Office Action of March 10, 2005 has been received and reviewed. Claims 2-13, 17-19 and 22-40 are currently pending in the application. Claims 1, 14-16, 20 and 21 were previously canceled. Claims 2-13, 17-19 and 22-40 stand rejected. Claims 2-13, 17 and 40 have been amended as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

#### Rejections Under 35 U.S.C. § 112, First Paragraph

Claim 40 stands rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the enablement requirement. (See, Office Action of March 10, 2005, at page 2, hereinafter referred to as, "Office Action"). Applicant traverses the rejection as set forth herein.

Specifically, it was thought that the specification enabled treatment of "skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hemotomas, hemorrhoids," but "does not reasonably provide enablement for treating herpes, rheumatism, arthrosis, and skin cancer." (See, Office Action, at page 2). As stated in the M.P.E.P. at § 2106.C, "[c]laims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements."

Claim 40 is directed to a method of treating, *inter alia*, herpes, rheumatism, arthrosis or skin cancer comprising administering to a patient a pharmaceutically effective amount of the preparation as described in claim 2 or claim 3. Claim 2 and claim 3, as amended, are directed to a preparation for topical application comprising, *inter alia*, at least one secondary plant

substance selected from the group consisting of carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes, phytoestrogens, sulfides, phytic acid and combinations thereof. Secondary plant substances (bioactive substances) are known foodstuffs.

The effects of secondary plant substances in foodstuffs have been investigated and reported and are well known in the art. Thus, applicant is not required to disclose these properties. (*See, Specification*, as filed, at page 1, third paragraph and page 2, third paragraph). The reference of B. Watzl, C. Leitzmann, entitled "Bioaktive Substanzen in Lebensmitteln (roughly translated in English to be "Bioactive Substances in Foodstuffs"), at Tables 1-6, indicates the effects of specific classes of secondary plant substances. (Hippokrates Verlag GmbH, Stuttgart, 1995, page 17). As can be seen from column B of Table 1-6, saponins, polyphenols, sulfides and phytic acid have antimicrobial effects and, therefore, are suitable for the treatment of herpes. (*Id.*).

Additionally, column A of Table 1-6 indicates classes of secondary plant substances that have anticarcinogenic effects, thus supporting the use of these substances in the treatment of skin cancer. (*Id.*).

The compounds listed in column F of Table 1-6, particularly the polyphenols and sulfides, exhibit anti-inflammatory effects. (*Id.*). Thus, these compounds are suitable for the treatment of rheumatism and arthrosis, as recited in claim 40.

Furthermore, the preparation for topical application, as recited in claim 3, further recites at least one polyunsaturated fatty acid of vegetable sources. This would encompass, *inter alia*, for instance,  $\omega$ -3- and  $\omega$ -6-fatty acids. Inflammatory effects of polyunsaturated fatty acids are known in the art. (*See, Specification*, as filed, for instance, at page 2, last paragraph). Thus, a person of ordinary skill in the art would expect that preparations for topical application

containing, for instance,  $\omega$ -3- and  $\omega$ -6-fatty acids, in addition to polyphenols or sulfides would be useful for the treatment of rheumatism and arthrosis.

As evidenced by the Watzl et al. reference, effects of secondary plant substances are well known to a person of ordinary skill in the art. Therefore, claim 40 does not require undue experimentation for a person of ordinary skill in the art to practice the invention.

Reconsideration and withdrawal of the enablement rejection of claim 40 is respectfully requested.

#### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 2-13, 17-19 and 22-40 stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, at page 4). In view of the amendments to claims 2 and 3, applicant traverses the rejection as set forth herein.

Specifically, it was though that the independent claims 2 and 3 were indefinite for reciting the term “phytin acid.” (*Id.*). Although applicant does not agree that the claims are indefinite, to expedite prosecution, applicant has amended claims 2 and 3 to recite, *inter alia*, “phytic acid” instead of “phytin acid,” as suggested. (*Id.*).

Dependant claims 4-13, 17-19 and 22-40 are not indefinite as, *inter alia*, depending from definite base claims, amended claims 2 and 3.

Reconsideration and withdrawal of the indefiniteness rejection of claims 2-13, 17-19 and 22-40 are requested.

**Rejections Under 35 U.S.C. § 102(b)**

Anticipation based on Abad, U.S. Patent No. 5,538,740

Claims 2, 7-9, 11, 17-19, 30-35 and 38-40 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by U.S. Patent No. 5,538,740 to Abad (hereinafter referred to as "Abad"). (See, Office Action, at page 5). Partly in view of the amendment made to claim 2, applicant traverses the rejections as set forth herein.

Abad describes a method for preparing an active ingredient for use in a therapeutic or cosmetic composition, said composition comprising gastropod secretions comprising a mixture of amino acids and non-toxic substances (cf. claim 1). Example III of Abad describes that the glandular secretions comprise a multiplicity of amino acids as well as a toxic substances. Example IV of Abad describes an excipient comprising, *inter alia*, calcium carbonate and zinc oxide. Example XIV of Abad describes the preparation of a deodorant cream, said cream comprising the glandular secretion of Example III, the excipient of Example IV, boric acid, menthol, chlorophyll and phormol.

Specifically, it was suggested that applicant amend the claims to recite "at least one individual amino acid in pure form." Although applicant does not agree that Abad anticipates independent claim 2, to expedite prosecution, claim 2 has been amended to recite, in part, "at least one individual amino acid in pure form, with the proviso that the amino acid is not an amino acid derivative."

Abad also does not disclose an excipient comprising zinc oxide and thus cannot anticipate the present invention.

Abad indicates in claim 1 and in Example III that the glandular secretions comprise a multiplicity of amino acids and, in addition thereto, allegedly non-toxic substances that are not further identified. All preparations disclosed in Abad comprise the gastropod secretion, the gastropod secretion itself comprising a multiplicity of arbitrary amino acids and additional unidentified substances. In contrast to the present invention, Abad does not disclose a composition comprising a specifically selected amino acid or a specific mixture of amino acids in pure form, without additional glandular secretion compounds.

Additionally, Abad does not disclose preparations comprising an individual amino acid in pure form or a preparation comprising a mixture of zinc oxide and an inorganic peroxide in addition to secondary plant substances, as disclosed by independent, amended claim 2. Thus, for the reasons given above, *inter alia*, Abad cannot anticipate amended, independent claim 2.

Dependent claims 7-9, 11, 17-19, 30-35 and 38-40 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, amended claim 2.

Reconsideration and withdrawal of the anticipation rejection of claims 2, 7-9, 11, 17-19, 30-35 and 38-40 are respectfully requested.

### **Rejections Under 35 U.S.C. § 103(a)**

#### Obviousness Rejections Based on U.S. Patent No. 5,667,791 to Hersh et al.

Claims 2-9, 11, 13, 17-19, 22-35 and 38-40 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent No. 5,667,791 to Hersh et al. (hereinafter

referred to as “Hersh et al.”). (Office Action, at page 6). Partly in view of the amendments made to claims 2 and 3, applicant traverses the rejections as hereinafter set forth.

M.P.E.P. § 706.02(j) sets forth the standard for an obviousness rejection as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Hersh et al. describes a composition comprising L-selenomethionine and glutathione, formulated to reduce X-ray radiation-induced skin damage, in a suitable carrier for topical application wherein said L-selenomethionine and said glutathione are present in a carrier in specific concentrations (c.f. claim 1). Selenomethionine used by Hersh et al. is 2-amino(methylselenyl)butyric acid. Glutathione is a tripeptide.

Specifically, it was believed that although Hersh et al. does not disclose zinc oxide, the use of zinc oxide in such compositions would be obvious to one of ordinary skill in the art. (Office Action, at page 6). Although applicant does not agree that the present invention is obvious in light of Hersh et al., to expedite prosecution, claims 2 and 3 have been amended to recite, in part, a “preparation for topical application comprising . . . zinc oxide and an inorganic peroxide.” Hersh et al. does not disclose the use of a combination of both zinc oxide and an inorganic peroxide, as recited, in part, in amended claims 2 and 3. Thus, since Hersh et al. does

not teach or suggest all of the elements of amended independent claims 2 and 3, amended independent claims 2 and 3 are not obvious in light of Hersh et al.

Furthermore, although applicant maintains that one of ordinary skill in the art would interpret the term "amino acid" to only proscribe individual, unaltered and underivitized, amino acids and thus not include the amino acid derivative selenomethionine, as evidenced by references that were submitted in the prior amendment and that clearly defined the state of the art, claims 2 and 3 have been amended to recite, in part, "at least one individual amino acid in pure form, with the proviso that the amino acid is not an amino acid derivative." Hersh et al. does not teach or suggest this element and thus, for this additional reason, claims 2 and 3 are not obvious in light of Hersh et al.

Dependent claims 4-9, 11, 13, 17-19, 22-35 and 38-40 are non-obvious, *inter alia*, as depending from non-obvious base claims, amended independent claims 2 and 3.

Reconsideration and withdrawal of the obviousness rejection of claims 2-9, 11, 13, 17-19, 22-35 and 38-40 are requested.

Obviousness Rejections Based on U.S. Patent No. 5,296,500 to Hillebrand

Claims 2, 6-7, 9-12, 17-19, 28-31 and 34-40 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent No. 5,296,500 to Hillebrand (hereinafter referred to as "Hillebrand"). (Office Action, at page 8). Partly in view of the amendments to claims 2 and 3, applicant traverses the rejections as hereinafter set forth.

Hillebrand describes a method of regulating wrinkles and atrophy in mammalian skin comprising treating skin with a composition comprising an amount of N-acetyl-L-cysteine, or a

pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier (cf. claim 1). In a preferred embodiment the composition of Hillebrand is rendered substantially odorless by additionally comprising a zinc salt. Hillebrand indicates that zinc most likely removes odor by competing with malodorous  $\text{H}_2\text{S}$ , which may be formed in trace amounts by the decomposition of *N*-acetyl-L-cysteine; (cf. column 3, last paragraph). Other conventional skin care product additives may also be included in the composition of Hillebrand (cf. column 7, penultimate paragraph).

Specifically, it was believed that though Hillebrand does not disclose the use of a plant substance, one of ordinary skill in the art would find it obvious to do so. (Office Action, at page 9). Although applicant does not agree that the present invention is obvious in light of Hillebrand, to expedite prosecution, claims 2 and 3 have been amended to recite, in part, a “preparation for topical application comprising . . . zinc oxide and an inorganic peroxide.” Hillebrand does not disclose the use of a combination of both zinc oxide and an inorganic peroxide, as recited, in part, in amended claims 2 and 3. Thus, since Hillebrand does not teach or suggest all of the elements of amended independent claims 2 and 3, amended independent claims 2 and 3 are not obvious in light of Hillebrand.

Furthermore, amended claims 2 and 3 recite, in part, “at least one individual amino acid in pure form, with the proviso that the amino acid is not an amino acid derivative.” Hillebrand discloses use of *N*-acetyl-L-cysteine. As is well known by one of ordinary skill in the art, *N*-acetyl-L-cysteine is an amino acid derivative. Thus, since Hillebrand neither teaches nor suggests all of the elements of the present invention as claimed, the present invention is not obvious in light of Hillebrand.



Moreover, since Hillebrand does not teach or suggest the use of an individual unsubstituted amino acid, a combination of zinc oxide and an inorganic peroxide, or a mixture of these three components, alone or in combination with at least one secondary plant substance, the subject matter of amended claims 2 and 3 cannot be obvious to a person of ordinary skill in the art in light of the disclosure of Hillebrand.

Dependent claims 6-7, 9-12, 17-19, 28-31 and 34-40 are non-obvious, *inter alia*, as depending from non-obvious base claims, amended independent claims 2 and 3.

Reconsideration and withdrawal of the obviousness rejection of claims 2, 6-7, 9-12, 17-19, 28-31 and 34-40 are requested.

Obviousness Rejections Based on U.S. Patent No. 5,378,461 to Neigut

Claims 2-4, 6, 7, 9-11, 13, 17-19, 22-25, 28-31 and 34-40 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over U.S. Patent No. 5,378,461 to Neigut (hereinafter referred to as "Neigut"). (Office Action, at page 8). Partly in view of the amendments to claims 2 and 3, applicant traverses the rejections as hereinafter set forth.

Neigut describes a balm for topical treatment of skin damage comprising a mixture of carrier, certain vitamins, and coenzyme Q<sub>10</sub> (cf. claim 1). Example 5 of Neigut discloses a composition comprising vitamins A, D and E, coenzyme CoQ<sub>10</sub>, L-cysteine, L-methionine, zinc oxide and corn starch (cf. table of Example 5). Corn starch has been used as an effective binder for all ingredients. Neigut does not teach or suggest a preparation for topical application comprising zinc oxide and an inorganic peroxide. Additionally, there is no hint in Neigut that

by using zinc oxide and an inorganic peroxide, high osmotic pressure can be provided and controlled.

Specifically, it was believed that although Neigut does not disclose the use of a plant substance, one of ordinary skill in the art would find it obvious to do so. (Office Action, at page 11). However, one of ordinary skill in the art knows that starch, as disclosed by Neigut, is *not a secondary plant substance*. Although applicant does not agree that the present invention is obvious in light of Neigut, to expedite prosecution, claims 2 and 3 have been amended to recite, in part, a “preparation for topical application comprising . . . zinc oxide and an inorganic peroxide.” Neigut does not disclose the use of a combination of both zinc oxide and an inorganic peroxide, as recited, in part, in amended claims 2 and 3. Thus, since Neigut does not teach or suggest all of the elements of amended independent claims 2 and 3, amended independent claims 2 and 3 cannot be obvious in light of Neigut.

Dependent claims 4, 6, 7, 9-11, 13, 17-19, 22-25, 28-31 and 34-40 are non-obvious, *inter alia*, as depending from non-obvious base claims, amended independent claims 2 and 3.

Reconsideration and withdrawal of the obviousness rejection of claims 2-4, 6, 7, 9-11, 13, 17-19, 22-25, 28-31 and 34-40 are requested.

Obviousness Rejections Based on U.S. Patent No. 5,378,461 to Neigut in Light of U.S. Patent No. 5,468,496 to Touzan et al.

Claims 5, 26 and 27 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Neigut in light of U.S. Patent No. 5,468,496 to Touzan et al. (hereinafter

referred to as “Touzan et al.”). (Office Action, at page 12). Partly in view of the amendments to claims 2 and 3, applicant traverses the rejections as hereinafter set forth.

Touzan et al. describes a cosmetic or dermatological composition comprising an aqueous phase and a separate oily phase, at least one of said phases containing a surfactant, said aqueous phase containing a demixing agent having a specific formula. Touzan et al. teaches that by combining a surfactant and a particular demixing agent, compositions that emulsify readily on shaking and whose constituents segregate rapidly on standing are obtained (cf. column 2, lines 53-57).

Specifically, it was believed that although Neigut does not disclose the use of tego-betaine, Touzan et al. discloses use of tego-betaine as a preferred surfactant. (*Id.*). Claim 5 depends from claims 2 and 4. Claim 4 also depends from claim 2. Claims 26 and 27 depend from claim 5. Since independent claim 2 is patentable over Neigut in light of Touzan, et al., it follows that dependent claims thereto, namely claims 5, 26 and 27, are also patentable over Neigut in light of Touzan et al.

Furthermore, amended claim 2 recites, in part, “at least one individual amino acid in pure form, with the proviso that the amino acid is not an amino acid derivative.” Neither Neigut nor Touzan et al. teaches nor suggests a composition comprising at least one individual, non-derivatized amino acid, zinc oxide, an inorganic peroxide or a secondary plant substance. Thus, the present invention cannot be obvious in light of Neigut in combination with Touzan et al.

Additionally, the teaching of Touzan et al. is based on compositions which emulsify readily on shaking and whose constituents segregate rapidly on standing. These compositions are entirely different from compositions of Neigut. The Touzan et al. compositions do not contain

amino acids, zinc oxide or particularly corn starch. Corn starch is used in Neigut as an effective binder to all ingredients. That is, Neigut's compositions are one-phase compositions. In contrast, the Touzan et al. compositions are two-phase compositions. Thus, Neigut and Touzan et al. teach entirely different classes of compositions. Therefore, a person of ordinary skill in the art has no motivation to combine Touzan et al. and Neigut. To do so could only be based on hindsight, which is an inappropriate basis for an obviousness rejection.

Reconsideration and withdrawal of the obviousness rejection of dependent claims 5, 26 and 27 are requested.

### CONCLUSION

In view of the foregoing amendments and remarks, applicants believe the claims define patentable subject matter and a notice of allowance is requested. If any questions remain after consideration of the foregoing, the Office is invited to contact the applicant's attorney at the address or telephone number given herein.

Dated: September 12, 2005

Respectfully submitted,

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